

## **REMARKS/ARGUMENTS**

The Office Action mailed June 1, 2006 has been received and reviewed. Claims 1-31 have been cancelled. Claims 32-52 have been added to the application. Applicants submit that no new matter has been added to this Application. Reconsideration of the present Application in view of the new claims and following remarks is respectfully requested.

### **Rejections based on 35 U.S.C. § 101**

The Examiner has rejected claims 1-31 under 35 U.S.C. § 101 for lack of patentable utility. Applicants submit that claims 1-31 have been cancelled and therefore the §101 rejection of these claims is moot.

### **Rejections based on 35 U.S.C. § 112, first paragraph**

Claims 1-31 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Applicants submit that claims 1-31 have been cancelled and therefore the §112 rejection of these claims is moot.

### **Rejections based on 35 U.S.C. § 112, second paragraph**

Claims 1-31 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants submit that claims 1-31 have been cancelled and therefore the §112 rejection of these claims is moot.

### **Rejections based on 35 U.S.C. § 102(a)**

Claims 1-11, 14, and 17-27 stand rejected under 35 U.S.C. § 102(a) as being anticipated by US 2003/013727 to Girn (hereinafter the “Girn reference”). Applicants submit that the §102(a) rejection is moot as claims 1-31 have been cancelled.

With respect to new claims 32-52, new independent claim 32 is directed to a method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises receiving a request from a clinician for genetic test results for a gene for a person and querying a first database to determine if the person has one or more genetic test results for the gene in response to the request by the clinician. The method further comprises obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. The one or more genetic test results of the at least one family member are utilized to calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. The calculated likelihood the person has a mutated form of the gene is presented to the clinician. *See Specification at paragraphs [0046]-[0048], [0050-0055], [0059]-[0060], and [0065], and FIG. 2B.*

New independent claim 41 is directed to a computer system for determining and presenting the likelihood a person has a mutated form of a gene. The computer system comprises a receiving module for receiving a request from a clinician for genetic test results for a gene for a person and a first querying module for querying a first database to determine if the person has one or more genetic test results for the gene in response to the request by the clinician. The system further comprises an obtaining module for obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene and a second querying module for querying a second database to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. A utilizing module utilizes the one or more genetic test results of the at least one family member to calculate a likelihood the person has a mutated form of the gene if at least one

of the family members has genetic test results for the gene. A presenting module presents the calculated likelihood the person has a mutated form of the gene to the clinician. *See Specification at paragraphs [0020], [0046]-[0048], [0050-0055], [0059]-[0060], and [0065], and FIG.2B.*

New independent claim 49 is directed to a method for determining and presenting the likelihood a person has a mutated form of a gene. The method comprises querying a database to determine if the person has one or more genetic test results for the gene in response to an order for medication for a person and obtaining the mode of inheritance for the gene if the person does not have one or more genetic test results for the gene. A database is queried to determine whether at least one family member of the person within the mode of inheritance has one or more genetic test results for the gene. The one or more genetic test results of the at least one family member are utilized to calculate a likelihood the person has a mutated form of the gene if at least one of the family members has genetic test results for the gene. The calculated likelihood the person has a mutated form of the gene is presented to a clinician. *See Specification at paragraphs [0046]-[0048], [0050-0055], [0059]-[0060], and [0066], and FIG. 2B.*

The Girn reference involves a process of entering a “family history” into a computer. *See, Girn Reference* at paragraph [0030]. Girn is directed to a process by which an individual may generate family history information to determine whether an individual is a candidate for genetic testing. The individual selects to record information relating to a particular disease or group of disease. *See, Girn Reference* at paragraph [0030]. For each member of the family, the individual is asked to provide demographic together with historical and current health status data that is specific to the disease. *See, Girn Reference* at paragraph [0031]. After the data is input by the individual, the data is analyzed to determine if the individual is at risk of

developing the selected illness. *See, Girn Reference* at paragraph [0031]. Clearly, the data in the Girn reference is analyzed to determine if the individual is at risk of developing the selected illness in response to the inputs by the individual.

On the other hand, according to claim 32 and claim 41 of the current application, if it is determined that a person does not have genetic test results for a gene, a likelihood calculation that a person has a mutated form of a gene is automatically provided to a clinician in response to the request by a clinician for genetic test results for the gene for the person. In this scenario, the clinician is not requesting the likelihood calculation. Rather, the clinician is requesting genetic test results for the person, not a likelihood calculation. The likelihood calculation is automatically provided if it is determined that the person not have genetic test results for the gene. Similarly, with respect to new claim 49, if it is determined that a person does not have genetic test results for a gene, a likelihood calculation that a person has a mutated form of a gene is automatically provided to a clinician in response to an order for medication for the person. New claims 32-52 are directed to a system and method that automatically performs queries on a person's family genetic test results in the absence of a person's genetic test results.

#### **Rejections based on 35 U.S.C. § 103(a)**

Claims 12-13, 15-16, and 28-31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Girn reference in view of US 2003/0108938 to Pikar (hereinafter the "Pikar reference"). Applicants submit that the §102(a) rejection is moot as claims 1-31 have been cancelled.

With respect to new claims 32-52, as discussed above, the Girn reference does not teach or suggest all the features of new independent claims 32, 42 and 49. Likewise, the Pikar reference does not teach or suggest a system and method that automatically performs queries on a person's family genetic test results in the absence of a person's genetic test results. Rather, the

Pikar reference teaches methods for clinical trials for linking biological information to the conduct and success of the clinical trial process for therapeutic agents. *See, Pikar Reference at Abstract.*

### **CONCLUSION**

Applicants submit that new claims 32-52 are in condition for allowance. If any issues remain that would prevent issuance of this Application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action. The Commissioner is hereby authorized to charge any additional amount required (or credit any overpayment) to Deposit Account No. 19-2112.

Respectfully submitted,

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